

ADOPTED: 22 March 2023

doi: 10.2903/j.efsa.2023.7967

Flavouring Group Evaluation 217 Revision 3 (FGE.217Rev3): consideration of genotoxic potential for α,β -unsaturated ketones and precursors from chemical subgroup 4.1 of FGE.19: lactones

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Abstract

The Panel on Food Additives and Flavourings of the European Food Safety Authority was requested to evaluate the genotoxic potential of four flavouring substances [FL-no: 10.023, 10.030, 10.057 and 13.012] from subgroup 4.1 of FGE.19. For three of these substances [FL-no: 10.023, 10.030 and 13.012], the concern for genotoxicity has been ruled out in previous revisions of Flavouring Group Evaluation 217 (FGE.217). However, in FGE.217Rev2, a concern for genotoxicity could not be ruled out for 3a,4,5,7a-tetrahydro-3,6-dimethylbenzofuran-2(3H)-one [FL-no: 10.057]. After publication of FGE.217Rev2, industry provided additional genotoxicity studies for [FL-no: 10.057], which are evaluated in the present opinion FGE.217Rev3. The flavouring substance [FL-no: 10.057] did not induce gene mutations or numerical or structural chromosomal aberrations *in vitro*. Based on these data, the Panel concluded that the concern for genotoxicity is ruled out for [FL-no: 10.057]. Consequently, it can be evaluated through the Procedure.

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Keywords: FGE.217, α,β -unsaturated ketones, lactones, flavouring substances, subgroup 4.1, FGE.19

Requestor: European Commission

Question number: EFSA-Q-2022-00537

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Suggested citation: EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings), Younes M, Aquilina G, Castle L, Degen G, Engel K-H, Fowler PJ, Frutos Fernandez MJ, Fürst P, Gundert-Remy U, Gürtler R, Husøy T, Manco M, Moldeus P, Passamonti S, Shah R, Waalkens-Berendsen I, Wright M, Benigni R, Bolognesi C, Chipman K, Cordelli E, Carfi M and Mennes W, 2023. Scientific Opinion on the flavouring Group Evaluation 217 Revision 3 (FGE.217Rev3): consideration of genotoxic potential for α , β -unsaturated ketones and precursors from chemical subgroup 4.1 of FGE.19: lactones. *EFSA Journal* 2023;21(4):7967, 16 pp. <https://doi.org/10.2903/j.efsa.2023.7967>

ISSN: 1831-4732

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The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.



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